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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/016,481 | 11/01/2001 | Qun-Yong Zhou | P-UC 5016 | 4599 |

23601 7590 01/29/2003

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EXAMINER

JIANG, DONG

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1646

DATE MAILED: 01/29/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,481

Applicant(s)

ZHOU ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 5-10, drawn to an isolated polypeptide having SEQ ID NO:3, a variant or fragment thereof, and a composition thereof, classified in class 530, subclass 300.
- II. Claims 4 and 12-15, drawn to a chimeric polypeptide having SEQ ID NO:13, a nucleic acid encoding thereof, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 530, subclass 69.7.
- III. Claim 11, drawn to a method of stimulating GI smooth muscle with the polypeptide of SEQ ID NO:3, classified in class 514, subclass 2.
- IV. Claims 12-15, drawn to a nucleic acid encoding the polypeptide of SEQ ID NO:3, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 530, subclass 69.1.
- V. Claim 16, drawn to an antibody selectively binding to the polypeptide of SEQ ID NO:3, classified in class 530, subclass 387.9.
- VI. Claims 17-19 and 21-26, drawn to an isolated polypeptide having SEQ ID NO:6, a variant or fragment thereof, and a composition thereof, classified in class 530, subclass 300.
- VII. Claims 20 and 28-31, drawn to a chimeric polypeptide having SEQ ID NO:14, a nucleic acid encoding thereof, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 530, subclass 69.7.
- VIII. Claim 27, drawn to a method of stimulating GI smooth muscle with the polypeptide of SEQ ID NO:6, classified in class 514, subclass 2.
- IX. Claims 28-31, drawn to a nucleic acid the polypeptide of SEQ ID NO:6, a vector containing same, a host cell thereof, and a method of recombinantly producing the

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encoded polypeptide, classified in class 530, subclass 69.1.

- X. Claim 32, drawn to an antibody the polypeptide of SEQ ID NO:6, classified in class 530, subclass 387.9.
- XI. Claims 33-36, 37 in part, and 38-46, drawn to a method of identifying a prokineticin receptor agonist, classification depending upon the chemical entity of the agonist.
- XII. Claims 33-36, 37 in part, 38-41, and 47-52, drawn to a method of identifying a prokineticin receptor antagonist, classification depending upon the chemical entity of the antagonist.

The inventions are distinct, each from the other because:

Invention I is distinct from and unrelated to invention II because they are physically and functionally distinct chemical entities. The method of Invention II is distinct from and unrelated to the polypeptide of Invention I because the polypeptide may be neither made by nor used in the method.

Invention I is related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the antibody of Invention IV.

The polypeptide of Invention I is related to the nucleic acid of Invention IV by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecule and the protein are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention IV is related to the protein of Invention I as process of making and product made. The Inventions are distinct if either or both of the following can be shown:

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(1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The polypeptide of Invention I is related to the antibody of Invention V by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Inventions II and III are distinct and unrelated, wherein the products of Invention II can be neither made by nor used in the method of Invention III, and wherein each does not require the other.

Invention II is distinct from and unrelated to inventions IV and V because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

Invention III is distinct from and unrelated to Inventions IV and V, wherein the nucleic acid of Invention IV, and the antibody of Invention V can be neither made by nor used in the method of Invention III, and wherein each does not require the other.

The nucleic acid of Invention IV is distinct from and unrelated to the antibody of Invention V because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention IV is distinct from and unrelated to the antibody of Invention V because the antibody may be neither made by nor used in the method.

The same reasoning and logic above applies to the restriction between groups of inventions VI-X.

Inventions I-V are distinct from Inventions VI-X as they are directed to different polypeptides (SEQ ID NO:3 or 13 vs. SEQ ID NO:6 or 14), or nucleic acids encoding thereof. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Inventions I, II, IV and V are distinct from and unrelated to Inventions IX and X, wherein the polypeptide of Invention I, the nucleic acids of Invention II or IV, or the antibody of Invention V can be neither made by nor used in the methods of Inventions XI and XII, and wherein each does not require the other.

Invention III is distinct from and unrelated to Inventions XI and XII because Invention III has different process steps, different active agents, different starting and ending points, and is for a different purpose from those of Inventions XI and XII, such that they require separate searches.

Inventions VI, VII, IX and X are distinct from and unrelated to Inventions XI and XII, wherein the polypeptide of Invention VI, the nucleic acid of Invention VII or IX, or the antibody of Invention X can be neither made by nor used in the methods of Inventions XI and XII, and wherein each does not require the other.

Invention VIII is distinct from and unrelated to Inventions XI and XII because Invention VIII has different process steps, different active agents, different starting and ending points, and is for a different purpose from those of Inventions XI and XII, such that they require separate searches.

Invention XI is distinct from Invention XII, wherein the method of Invention XI is for identifying a receptor *agonist*, whereas the method of Invention XII is for identifying a receptor *antagonist*, thus they require different active compounds, and are for different purposes, such that requiring separate searches.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
1/22/03